

Application No.: 09/991,151

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**REMARKS****Interview request**

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at 858 720 5133.

**Status of the Claims*****Pending claims***

Claims 1 to 48 are pending (please note: page 1 status section of the office action lists claims 1 to 22 and 36 to 48 as pending; actually, claims 23 to 35, only have been withdrawn). Accordingly, claims 1 to 21 and 36 to 48 are pending and under consideration.

***Outstanding Rejections***

Claims 1 to 21 and 36 to 48 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Wright, et al., USPN 5,087,360, issued February 11, 1992, in view of Luque de Castro (1999) Trends in Analytical Chem. 19:708-716.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims. Reconsideration of the pending claims is respectfully requested.

**Support for the Claim Amendments**

The specification sets forth an extensive description of the invention in the new and amended claims. For example, support for claims directed to methods wherein the sample comprises a solid or a semi-solid sample can be found, inter alia, on page 3, in the second paragraph of the Summary. Support for claims directed to methods wherein microwave energy is or is not used, and optionally is used to heat the sample, the solvent or the extraction cell, can be found, inter alia, on page 3, in the third paragraph of the Summary. Support for claims directed to methods wherein the solvent is maintained under the regulated pressure or pressure range by an in-line back pressure regulator positioned downstream of the extraction cell can be found, inter alia, on page 3, in the second paragraph of the Summary (see lines 8 to 10 of the paragraph). Support for claims

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directed to methods wherein the analytical device comprises a capillary electrophoresis (CE) or a high performance liquid chromatography (HPLC) can be found, inter alia, on page 5, first paragraph of the Detailed Description. Accordingly, no new matter has been added by way of these amendments and support for each amendment can be found in the original claims as filed and throughout the specification.

Issues under 35 U.S.C. §103(a)

Claims 1 to 21 and 36 to 48 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Wright, et al., USPN 5,087,360, issued February 11, 1992 ("Wright"), in view of Luque de Castro (1999) Trends in Analytical Chem. 19:708-716 ("Luque").

The legal standard for determining obviousness has been summarized by the Federal Circuit in In re Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002):

The essential factual evidence on the issue of obviousness is set forth in Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors).

"The factual inquiry whether to combine references must be thorough and searching." Id. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential component of an obviousness holding'") (quoting C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998)); In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."); In re Dance,

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160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) ("teachings of references can be combined only if there is some suggestion or incentive to do so.") (emphasis in original) (quoting ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)).

... the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (the examiner can satisfy the burden of showing obviousness of the combination "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references").

Thus, in order to establish a *prima facie* case of obviousness under section 103(a), the Patent Office must show that some objective teaching, motivation, or suggestion in the applied prior art taken as a whole and/or knowledge generally available to one of ordinary skill in the art would have led that person to the claimed invention as a whole, including each and every limitation of the claims, without recourse to the teaching in the specification. See also In re Rouffet, 149 F.3d 1350, 1358, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).

Applicants respectfully submit, for reasons set forth in detail below, that because the Patent Office did not sufficiently explain reasons why one of ordinary skill in the art would have been motivated to select the cited references and to combine them to render the claimed invention obvious, the Patent Office did not show a proper *prima facie* case of obviousness, and the rejection should be withdrawn.

Claim 1, the only pending independent claim, is directed to methods for solvent extraction of an organic analyte from a sample comprising, inter alia, contacting the sample with a preheated organic solvent system comprising an extraction fluid, wherein the extraction fluid is under conditions comprising elevated temperature and regulated pressure within a specified range or at a specified value to non-selectively extract the analytes, and the organic solvent system is in liquid form under conditions comprising elevated temperature and pressure during extraction.

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The Patent Office interprets Wright as not teaching a pressure regulation system that includes an in line back pressure regulator or equivalent positioned downstream of the extraction cell. Applicants agree – the Wright reference is defective in that it does not teach a method or system regulating pressure or pressure ranges in the extraction cell by means of an in-line back pressure regulator positioned downstream of the extraction cell. In Wright, a pressure control module is placed inside a high pressure pump positioned upstream of the extraction cell (see, e.g., column 5, lines 16 to 33).

By nature of the upstream positioning of the pressure control module, the method and apparatus of Wright cannot maintain the regulated pressure that is possible when an in-line back pressure regulator, or equivalent, is positioned downstream of the extraction cell. However, nowhere in Wright is there any teaching or suggestion recognizing this problem in organic extraction systems (solved by the instant invention). In Wright is there no teaching or suggestion regarding the desirability of making an organic solvent-based extraction system having an in-line back pressure regulator, or equivalent, positioned downstream of an extraction cell. In fact, Wright teaches the desirability for locating a pressure control module inside a high pressure pump that is positioned upstream of an extraction cell.

The Patent Office alleges that Luque discloses a method for solvent extraction of analytes from plant samples comprising contacting a sample in an extraction cell with a preheated organic solvent (water, preheated coil in oven) as an extraction fluid under elevated temperatures and pressures to extract analytes from the samples, citing primarily pages 711 to 712 of Luque. It is noted that Luque uses a variable restrictor – equivalent to an in line pressure regulator – positioned downstream of an extraction chamber.

However, Luque does not disclose a method for solvent extraction of analytes comprising preheating an organic solvent as an extraction fluid. Pages 711 to 712 of Luque, in the section entitled CSWE, or “continuous subcritical water extraction”, is a technique based on the use of heated water (an aqueous solvent) as an extraction fluid. No preheated organic solvent is used as an extraction fluid in CSWE, or any other technique taught by Luque.

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Luque does discuss methods using organic solvents, inter alia, in the section entitled "Discontinuous convention techniques", page 709. However, none of the methods discussed by Luque comprise preheating an organic solvent as an extraction fluid. In fact, Luque teaches away from using an organic extraction technique, concluding "... most of them (such as organic solvent extraction and hydrodistillation) are difficult or impossible to manipulate in order to obtain a product with the desired characteristics. Nowhere in Luque is there any teaching or suggestion recognizing a pressure regulation problem in organic extraction systems, including the pressure regulation problem created by the configuration of the apparatus of Wright. Thus, Luque provides no teaching or suggestion regarding the desirability of using any organic extraction system, including organic extraction systems having an in-line back pressure regulator, or equivalent, positioned downstream of an extraction cell.

Accordingly, using Luque to cure the defects in Wright is a hindsight-based obviousness analysis. This is impermissible under the law. The Federal Circuit has stated:

It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." (quoting *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600).

In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). The present rejection fits the court's description of what may not be done under § 103. The Patent Office has merely combined two references having certain components of Applicants' invention to, in hindsight, reconstruct the instant claimed invention.

In summary, Luque does not teach or suggest recognizing a pressure regulation problem in organic extraction systems and Luque does not teach or suggest the desirability of using any organic extraction system, including organic extraction systems having an in-line back pressure regulators positioned downstream of an extraction cell. Thus, the Patent Office has not sufficiently explained reasons why one of ordinary skill in the art would have been motivated to select Wright

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and Luque and combine them to render the claimed invention obvious. Accordingly, the Patent Office did not show a proper *prima facie* case of obviousness and the rejection should be withdrawn.

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CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §103(a). In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket No. 532782000100.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858 720 5133.

Dated: June 10, 2005

Respectfully submitted,

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